

MAY 25 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K071215

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1. **Submitter name, address, contact** Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive MC00881
Rochester, New York 14626-5101
Phone: (585) 453-3143
FAX: (585) 453-3368
Email: mbyrne3@ocdus.jnj.com
Contact Person: Michael M. Byrne
 2. **Preparation date** May 1, 2007
 3. **Device name** Trade or Proprietary Name:
VITROS Chemistry Products urCR DT Slides
VITROS Chemistry Products DT Calibrator Kit

Common Name: VITROS urCR assay
Classification Name: Creatinine test system (21 CFR 862.1225).

Common Name: VITROS DT Calibrator Kit
Classification Name: Calibrator (21 CFR 862.1150)
 4. **Predicate device** The VITROS urCR assay (modified device) is substantially equivalent to the VITROS urCR assay (original device). The FDA cleared the VITROS Chemistry Products urCR DT Slides and VITROS Chemistry Products DT Calibrator Kit on March 21, 1994 (K934071) under the following product names:

KODAK EKTACHEM DT SLIDES (urCR) and
KODAK EKTACHEM DT Calibrator Kit

Note: With the purchase of KODAK Clinical Products Division by Johnson and Johnson, the product branding was revised to VITROS Chemistry Products urCR DT Slides and VITROS Chemistry Products DT Calibrator Kit.

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5. Device description

The VITROS urCR assay is performed using the VITROS Chemistry Products urCR DT Slides, and the VITROS Chemistry Products DT Calibrator Kit on VITROS DT60/DT60II Chemistry Systems.

The VITROS urCR Slide is a multilayered, analytical element coated on a polyester support.

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Creatinine diffuses to the reagent layer, where it is hydrolyzed to creatine in the rate-determining step. The creatine is converted to sarcosine and urea by creatine amidinohydrolase. The sarcosine, in the presence of sarcosine oxidase, is oxidized to glycine, formaldehyde, and hydrogen peroxide. The final reaction involves the peroxidase-catalyzed oxidation of a leuco dye to produce a colored product.

Following addition of the sample, the slide is incubated. During the initial reaction phase, endogenous creatine in the sample is oxidized. The resulting rate of change in reflection density is proportional to the concentration of creatinine in the sample.

Once a calibration has been performed for each slide lot, creatinine concentration in unknown samples can be determined using the software-resident rate math model and the change in reflectance calculated for each unknown test slide.

VITROS DT Calibrator Kit contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from processed bovine serum to which organic analytes, electrolytes, stabilizers, and preservatives have been added. The diluents are prepared from processed water to which inorganic salts have been added. Once reconstituted, the appropriate standards are used to calibrate VITROS DT60/DT60 II Chemistry Systems for the quantitative measurement of creatinine in urine.

Calibration of the VITROS urCR assay requires the use of bottles 1, 2 and 4 of the VITROS DT Calibrator Kit.

6. Device intended use

For *in vitro* diagnostic use only.

VITROS Chemistry Products urCR DT Slides quantitatively measure creatinine concentration in urine.

For *in vitro* diagnostic use only.

VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl, CO₂, CREA, CRSC, Fe, GGT, GLU, HDLC, K⁺, LAC, LDH, LIPA, Mg, Na⁺, NH₃, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

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- 7. Comparison to predicate device** The VITROS urCR assay (modified device) is substantially equivalent to the predicate, VITROS urCR assay (original), which was cleared by the FDA (K934071) for in vitro diagnostic use.

Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	Modified Device VITROS urCR assay (modified)	Predicate Device VITROS urCR assay (original)
Intended Use	No change	For <i>in vitro</i> diagnostic use only. VITROS urCR DT Slides quantitatively measure creatinine concentration in urine. For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl, CO ₂ , CREA, CRSC, Fe, GGT, GLU, HDLC, K ⁺ , LAC, LDH, LIPA, Mg, Na ⁺ , NH ₃ , PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.
Calibration traceability	The values assigned to the VITROS Chemistry Products DT Calibrator Kit for Creatinine are traceable to a Gas Chromatography Isotope Dilution Mass Spectrometry (GC/IDMS) method ¹ and NIST SRM [®] 914, creatinine standard reference material.	Traceable to Certified NIST (National Institute of Standards and Technology) Reference Material SRM [®] (Standard Reference Material) 914a.
Reference Interval (Urine)	Males: 1000 – 2000 mg/day ² Females: 800 – 1800 mg/day ²	800 – 2800 mg/day
Reportable range Urine	1.0 – 339.2 mg/dL* *After multiplying by a dilution factor of 21	2.1 – 346.5 mg/dL* *After multiplying by a dilution factor of 21
Sample type	No change	Urine
Basic principle	No change	Colorimetric rate
Instrumentation	No change	VITROS DTSC/DTSCII Module

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- 8. Conclusions** The information presented in the pre-market notification demonstrates that the performance of the VITROS urCR assay (modified device) for use with human urine is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with quality control fluids, proficiency samples, and human urine with measured creatinine values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS urCR assay (modified device) for use with human urine is safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics, Inc.
c/o Michael M. Byrne, RAC
Regulatory Affairs Associate
100 Indigo Creek Drive
Rochester, NY 14626-5101

MAY 25 2007

Re: k071215
Trade/Device Name: VITROS Chemistry Products urCR DT Slides,
VITROS Chemistry Products DT Calibrator Kit
Regulation Number: 21 CFR §862.1215
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY, JIX
Dated: May 1, 2007
Received: May 2, 2007

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

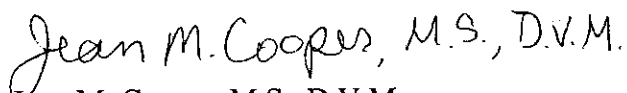
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Jean M. Cooper, M.S., D.V.M.".

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071215

Device Name: VITROS Chemistry Products urCR DT Slides

Indications for Use: For *in vitro* diagnostic use only.
VITROS urCR DT Slides quantitatively measure creatinine concentration in urine on the DT60/DT60 II analyzer.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K071215

Indications for Use

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Indications for Use: For *in vitro* diagnostic use only.
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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benham

Special Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K071215